

Regulation (EC) No 2160/2003 of the European Parliament
and of the Council of 17 November 2003 on the control of
salmonella and other specified food-borne zoonotic agents

REGULATION (EC) No 2160/2003 OF THE
EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 17 November 2003

on the control of salmonella and other specified food-borne zoonotic agents

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

Having regard to the proposal from the Commission⁽¹⁾,

Having regard to the opinion of the European Economic and Social Committee⁽²⁾,

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty⁽³⁾,

Whereas:

- (1) Live animals and food of animal origin appear on the list in Annex I to the Treaty. Livestock farming and the placing on the market of food of animal origin constitute an important source of income for farmers. The implementation of veterinary measures aimed at raising the level of public and animal health in the Community assists the rational development of the farming sector.
- (2) The protection of human health against diseases and infections transmissible directly or indirectly between animals and humans (zoonoses) is of paramount importance.
- (3) Zoonoses transmissible through food may cause human suffering, as well as economic losses to food production and the food industry.
- (4) Zoonoses transmitted through sources other than food, especially from wild animal and pet animal populations, are also a matter of concern.
- (5) Zoonoses present at the level of primary production must be adequately controlled to ensure that the objectives of this Regulation are achieved. However, in the case of primary production leading to the direct supply of small quantities of primary products, by the food business operator producing them, to the final consumer or to local shops, it is appropriate to protect public health through national law. In this case there is a close relationship between the producer and the consumer. Such production should not make a significant contribution to the average prevalence of zoonoses in animal populations in the Community as a whole. The general requirements for sampling and analysis may not be practical or appropriate for producers with very small numbers of animals who may be located in regions suffering from special geographical constraints.

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Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 2160/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

- (6) Council Directive 92/117/EEC of 17 December 1992 concerning measures for protection against specified zoonoses and specified zoonotic agents in animals and products of animal origin in order to prevent outbreaks of food-borne infections and intoxications⁽⁴⁾ provided for the establishment of monitoring systems for certain zoonoses and controls on salmonella in certain poultry flocks.
- (7) That Directive required Member States to submit to the Commission the national measures that they had taken to achieve the objectives of the Directive and to draw up plans for monitoring salmonella in poultry. However, Council Directive 97/22/EC⁽⁵⁾ amending Directive 92/117/EEC suspended the requirement pending the review provided for in Article 15a of Directive 92/117/EEC.
- (8) Several Member States have already submitted their plans for the monitoring of salmonella, which the Commission has approved. Moreover, all Member States were required, with effect from 1 January 1998, to fulfil the minimum measures laid down for salmonella in Annex III, Section I, to Directive 92/117/EEC, and to establish rules specifying the measures to be taken to avoid the introduction of salmonella on to a farm.
- (9) Those minimum measures focused on monitoring and controlling salmonella in breeding flocks of the species *Gallus gallus*. When serotypes *Salmonella enteritidis* or *Salmonella typhimurium* were detected and confirmed in samples taken, Directive 92/117/EEC laid down specific measures to control the infection.
- (10) Other Community legislation provides for the monitoring and control of certain zoonoses in animal populations. In particular Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine⁽⁶⁾ deals with bovine tuberculosis and bovine brucellosis. Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals⁽⁷⁾ deals with ovine and caprine brucellosis. This Regulation should not create any unnecessary duplication of these existing requirements.
- (11) Moreover, future Community legislation on food hygiene should cover specific elements necessary for the prevention, control and monitoring of zoonoses and zoonotic agents and include specific requirements for the microbiological quality of food.
- (12) Directive 92/117/EEC provided for the collection of data on the occurrence of zoonoses and zoonotic agents in feedingstuffs, animals, food and humans. That data collection system, although not harmonised and therefore not allowing comparison between Member States, does provide a basis for evaluating the current situation concerning zoonoses and zoonotic agents in the Community.
- (13) The results of the data collection system show that certain zoonotic agents, namely *Salmonella* spp. and *Campylobacter* spp., cause the majority of cases of zoonoses in humans. There seems to be a decreasing trend of human cases of salmonellosis, in particular due to *Salmonella enteritidis* and *Salmonella typhimurium*, thus reflecting the success of related control measures taken in the Community. Nevertheless, it is assumed that many cases remain unreported and therefore the data collected do not necessarily give the full picture of the situation.

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- (14) In its opinion on zoonoses adopted on 12 April 2000, the Scientific Committee on Veterinary Measures relating to Public Health considered that the measures in place at that time to control food-borne zoonotic infections were insufficient. It further considered that the epidemiological data that Member States were collecting were incomplete and not fully comparable. As a consequence, the Committee recommended improved monitoring arrangements and identified risk management options.
- (15) It is therefore necessary to improve the existing control systems for specific zoonotic agents. Simultaneously, the rules laid down in Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, amending Council Decision 90/424/EEC and repealing Council Directive 92/117/EEC⁽⁸⁾ will replace the monitoring and data collection systems established by Directive 92/117/EEC.
- (16) In principle, controls should cover the whole food chain, from farm to table.
- (17) The rules governing such controls should generally be those laid down under Community legislation on feedingstuffs, animal health and food hygiene.
- (18) However, for certain zoonoses and zoonotic agents it is necessary to lay down specific requirements for controls.
- (19) Those specific requirements should be based on targets for the reduction of the prevalence of zoonoses and zoonotic agents.
- (20) The targets should be established for zoonoses and zoonotic agents in animal populations taking account, in particular, of their frequency and epidemiological trends in animal and human populations, feed and food, their gravity for humans, their potential economic consequences, scientific advice and the existence of appropriate measures to reduce their prevalence. Targets may be established in respect of other parts of the food chain, where necessary.
- (21) To ensure the achievement of the targets in good time, Member States should set up specific control programmes, which the Community should approve.
- (22) The main responsibility for the safety of food should lie with food and feed business operators. Member States should, therefore, encourage the creation of business-wide control programmes.
- (23) Within their control programmes, Member States and food and feed business operators may wish to use specific control methods. However, certain methods may not be acceptable, in particular if they hamper the achievement of the target in general, interfere specifically with necessary testing systems or give rise to potential threats to public health. Appropriate procedures should therefore be laid down enabling the Community to decide that certain control methods should not be used as part of control programmes.
- (24) Control methods may also exist or be developed which, as such, do not fall under any specific Community legislation on product approval but would help to achieve the

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targets for the reduction of the prevalence of specified zoonoses and zoonotic agents. It should, therefore, be possible to approve the use of such methods at Community level.

- (25) It will be essential to ensure that restocking of animals takes place from flocks or herds that have been subject to controls in accordance with the requirements of this Regulation. When a specific control programme is in force, the results of testing should be forwarded to purchasers of animals. To that end, specific requirements should be added to the corresponding Community legislation on intra-Community trade and imports from third countries, in particular as regards consignments of live animals and hatching eggs. Directive 64/432/EEC, Council Directive 72/462/EEC of 12 December 1972 on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat from third countries⁽⁹⁾ and Council Directive 90/539/EEC of 15 October 1990 on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs⁽¹⁰⁾ should be amended accordingly.
- (26) The adoption of this Regulation should not affect the additional guarantees agreed for Finland and Sweden on their accession to the Community and confirmed by Commission Decisions 94/968/EC⁽¹¹⁾, 95/50/EC⁽¹²⁾, 95/160/EC⁽¹³⁾, 95/161/EC⁽¹⁴⁾, 95/168/EC⁽¹⁵⁾ and by Council Decisions 95/409/EC⁽¹⁶⁾, 95/410/EC⁽¹⁷⁾ and 95/411/EC⁽¹⁸⁾. This Regulation should provide a procedure for the granting, for a transitional period, of guarantees to any Member State that has an approved national control programme exceeding the minimum Community requirements in relation to salmonella. The results of tests on live animals and hatching eggs traded with such a Member State should meet the criteria laid down in its national control programme. Future Community legislation on hygiene rules for food of animal origin should provide a similar procedure in respect of meat and table eggs.
- (27) Third countries exporting to the Community must implement equivalent measures for the control of zoonoses at the same time as measures are applied in the Community.
- (28) As regards control of salmonella, available information tends to show that poultry products are a major source of human salmonellosis. Control measures should, therefore, be applied to production of those products, thus extending the measures initiated under Directive 92/117/EEC. As regards the production of table eggs, it is important to establish specific measures concerning the placing on the market of products originating from flocks that have not been tested free of relevant salmonella. As regards poultry meat, the aim is to place on the market poultry meat with reasonable assurance that it is free from relevant salmonella. A transitional period is necessary for food business operators to adapt to the measures envisaged, which may be adapted further in particular in the light of scientific risk assessment.
- (29) It is appropriate to designate national and Community reference laboratories to give guidance and assistance on matters falling within the scope of this Regulation.
- (30) To ensure the uniform application of this Regulation, provision should be made for the organisation of Community audits and inspections in accordance with other Community legislation in this field.

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- (31) Appropriate procedures should be laid down for amending certain provisions of this Regulation to take account of technical and scientific progress and for the adoption of implementing and transitional measures.
- (32) To take account of technical and scientific progress, close and effective cooperation should be ensured between the Commission and the Member States within the Standing Committee set up by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority, and laying down procedures in matters of food safety⁽¹⁹⁾.
- (33) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission⁽²⁰⁾,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

INTRODUCTORY PROVISIONS

Article 1

Subject matter and scope

- 1 The purpose of this Regulation is to ensure that proper and effective measures are taken to detect and to control salmonella and other zoonotic agents at all relevant stages of production, processing and distribution, particularly at the level of primary production, including in feed, in order to reduce their prevalence and the risk they pose to public health.
- 2 This Regulation shall cover:
- a the adoption of targets for the reduction of the prevalence of specified zoonoses in animal populations:
 - (i) at the level of primary production; and
 - (ii) where appropriate for the zoonosis or zoonotic agent concerned, at other stages of the food chain, including in food and feed;
 - b the approval of specific control programmes established by Member States and food and feed business operators;
 - c the adoption of specific rules concerning certain control methods applied in the reduction of the prevalence of zoonoses and zoonotic agents;
 - d the adoption of rules concerning intra-Community trade and imports from third countries of certain animals and products thereof.
- 3 This Regulation shall not apply to primary production:
- a for private domestic use; or
 - b leading to the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the primary products to the final consumer.

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4 Member States shall establish, under national law, rules governing the activities referred to in paragraph 3(b). Such national rules shall ensure that the objectives of this Regulation are achieved.

5 This Regulation shall apply without prejudice to more specific Community provisions on animal health, animal nutrition, food hygiene, communicable human diseases, health and safety in the workplace, gene technology and transmissible spongiform encephalopathies.

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

1. the definitions laid down in Regulation (EC) No 178/2002;
2. the definitions laid down in Directive 2003/99/EC; and
3. the following definitions:
 - (a) 'herd' means an animal or group of animals kept on a holding as an epidemiological unit; and
 - (b) 'flock' means all poultry of the same health status kept on the same premises or in the same enclosure and constituting a single epidemiological unit; in the case of housed poultry, this includes all birds sharing the same airspace.

Article 3

Competent authorities

1 Each Member State shall designate a competent authority or competent authorities for the purpose of this Regulation and notify the Commission thereof. If a Member State designates more than one competent authority, it shall:

- a notify the Commission of the competent authority that will act as a contact point for contacts with the Commission; and
- b ensure that the competent authorities cooperate so as to guarantee the proper implementation of the requirements of this Regulation.

2 The competent authority or authorities shall be responsible in particular for:

- a drawing up the programmes provided for in Article 5(1) and preparing any amendments thereto which prove necessary, in particular in the light of data and results obtained;
- b collecting the data needed to evaluate the means used and the results obtained in carrying out the national control programmes provided for in Article 5 and for submitting those data and results yearly, including the results of any surveys undertaken, to the Commission, having regard to the rules laid down pursuant to Article 9(1) of Directive 2003/99/EC;
- c carrying out regular checks on the premises of food and, if needed, feed businesses for the purpose of checking compliance with this Regulation.

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CHAPTER II

COMMUNITY TARGETS

Article 4

Community targets for the reduction of the prevalence of zoonoses and zoonotic agents

1 Community targets shall be established for the reduction of the prevalence of zoonoses and zoonotic agents listed in Annex I, column 1, in the animal populations listed in Annex I, column 2, taking account, in particular, of:

- a the experience gained under existing national measures; and
- b information forwarded to the Commission or to the European Food Safety Authority under existing Community requirements, in particular in the framework of information provided for in Directive 2003/99/EC, in particular Article 5 thereof.

The targets, and any amendments to them, shall be established in accordance with the procedure referred to in Article 14(2).

2 The targets referred to in paragraph 1 shall consist at least of:

- a a numerical expression of:
 - (i) the maximum percentage of epidemiological units remaining positive; and/or
 - (ii) the minimum percentage of reduction in the number of epidemiological units remaining positive;
- b the maximum time limit within which the target must be achieved;
- c the definition of the epidemiological units referred to in (a);
- d the definition of the testing schemes necessary to verify the achievement of the target; and
- e the definition, where relevant, of serotypes with public health significance or of other subtypes of zoonoses or zoonotic agents listed in Annex I, column 1, having regard to the general criteria listed in paragraph 6(c) and any specific criteria laid down in Annex III.

3 Community targets shall be established for the first time before the relevant dates indicated in Annex I, Column 4.

4

- a When defining each Community target, the Commission shall provide an analysis of its expected costs and benefits. This analysis shall take account, in particular, of the criteria laid down in paragraph 6(c). Member States shall, on request, provide the Commission with all the assistance necessary to enable it to prepare the analysis.
- b Before proposing each Community target, the Commission shall consult Member States within the committee referred to in Article 14(1) on the results of its analysis.
- c In the light of the results of that analysis and the consultation of Member States, the Commission shall propose Community targets where appropriate.

5 However, by way of derogation from paragraphs 2(e) and 4, the following rules shall apply to poultry for a transitional period.

The Community target established for breeding flocks of *Gallus gallus* for this transitional period shall cover the five most frequent salmonella serotypes in human salmonellosis, which shall be identified on the basis of data collected through EC

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monitoring systems. The Community targets established for laying hens, broilers and turkeys for the transitional period shall cover *Salmonella enteritidis* and *Salmonella typhimurium*. However, if necessary, these targets may be extended to other serotypes on the basis of the results of an analysis carried out in accordance with paragraph 4.

The transitional period shall apply to each Community target for the reduction of the prevalence of salmonella in poultry. It shall last for three years in each case, starting on the date mentioned in column 5 of Annex I.

6

- a Annex I may be amended, in accordance with the procedure laid down in Article 14(2), for the purposes listed in subparagraph (b), after taking account in particular of the criteria listed in subparagraph (c).
- b Amendments to Annex I may alter the scope of the requirements regarding the establishment of Community targets by supplementing, restricting or modifying:
 - (i) the zoonoses or zoonotic agents;
 - (ii) the stages of the food chain; and/or
 - (iii) the animal populations concerned.
- c The criteria to be considered before amending Annex I include, with respect to the zoonosis or zoonotic agent concerned:
 - (i) its frequency in animal and human populations, feed and food;
 - (ii) the gravity of its effects for humans;
 - (iii) its economic consequences for animal and human health care and for feed and food businesses;
 - (iv) epidemiological trends in animal and human populations, feed and food;
 - (v) scientific advice;
 - (vi) technological developments, particularly relating to the practicality of the available control options; and
 - (vii) requirements and trends concerning breeding systems and production methods.

7 Annex III may be amended or supplemented in accordance with the procedure referred to in Article 14(2).

8 The Commission shall review the implementation of Community targets and take account of this review when proposing further targets.

9 Measures taken to reduce the prevalence of zoonoses and zoonotic agents listed in Annex I shall be implemented in accordance with the rules laid down in this Regulation and any rules adopted pursuant thereto.

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CHAPTER III

CONTROL PROGRAMMES

Article 5

National control programmes

- 1 To achieve the Community targets provided for in Article 4, Member States shall establish national control programmes for each zoonosis and zoonotic agent listed in Annex I. National control programmes shall have regard to the geographical distribution of zoonoses within each Member State and to the financial implications for primary producers and feed and food business operators of establishing effective controls.
- 2 National control programmes shall be continuous and cover a period of at least three consecutive years.
- 3 National control programmes shall:
 - a provide for the detection of zoonoses and zoonotic agents in accordance with the requirements and minimum sampling rules laid down in Annex II;
 - b define the respective responsibilities of competent authorities and food and feed business operators;
 - c specify the control measures to be taken following the detection of zoonoses and zoonotic agents, in particular to protect public health, including implementation of the specific measures laid down in Annex II;
 - d allow for the progress under their provisions to be evaluated and for those programmes to be reviewed, in particular in the light of results obtained from the detection of zoonoses and zoonotic agents.
- 4 National control programmes shall cover at least the following stages of the food chain:
 - a feed production;
 - b primary production of animals;
 - c processing and preparation of food of animal origin.
- 5 National control programmes shall contain, where relevant, the provisions laid down in relation to testing methods and criteria against which the results of these tests shall be assessed, for testing animals and hatching eggs despatched within the national territory, as part of the official controls provided for in Annex II, part A.
- 6 The requirements and minimum sampling rules laid down in Annex II may be amended, adapted or supplemented, in accordance with the procedure referred to in Article 14(2), after taking account in particular of the criteria listed in point (c) of Article 4(6).
- 7 Within six months of the establishment of the Community targets provided for in Article 4, Member States shall submit their national control programmes to the Commission and set out the measures to be implemented.

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Article 6

Approval of the national control programmes

1 After a Member State submits a national control programme in accordance with Article 5, the Commission shall have two months within which to request any further relevant and necessary information from that Member State. The Member State shall provide such further information within two months of receiving such a request. The Commission shall, within two months of receiving such further information or, if it did not request further information, within six months of the submission of the control programme, establish whether it complies with relevant rules, including this Regulation in particular.

2 When the Commission has established the conformity of a national control programme, or at the request of the Member State that submitted it, the programme shall be considered without undue delay with a view to approval in accordance with the procedure referred to in Article 14(2).

3 Amendments to a programme previously approved pursuant to paragraph 2 may be approved, in accordance with the procedure referred to in Article 14(2), to take account of the evolution in the situation in the Member State concerned, in particular in the light of the results referred to in Article 5(3)(d).

Article 7

Food and feed business operators' control programmes

1 Food and feed business operators, or organisations representing such operators, may establish control programmes, covering, as far as possible, all stages of production, processing and distribution.

2 If they wish their control programmes to form part of a national control programme, food and feed business operators, or their representative organisations, shall submit their control programmes, and any amendments thereto, to the competent authority of the Member State in which they are located for approval. If the operations concerned take place in different Member States, the programmes shall be approved separately for each Member State.

3 The competent authority may approve control programmes submitted pursuant to paragraph 2 only if it is satisfied that the control programmes comply with the relevant requirements set out in Annex II and with the objectives of the relevant national control programme.

4 Member States shall maintain up-to-date lists of approved control programmes of food and feed business operators or their representative organisations. The lists shall be made available to the Commission upon request.

5 Food and feed business operators or their representative organisations shall communicate regularly the results of their control programmes to the competent authorities.

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CHAPTER IV

CONTROL METHODS

Article 8

Specific control methods

- 1 At the initiative of the Commission or at the request of a Member State and in accordance with the procedure referred to in Article 14(2):
 - a it may be decided that specific control methods may or shall be applied for the reduction of prevalence of zoonoses and zoonotic agents at the stage of the primary production of animals and other stages in the food chain;
 - b rules may be adopted concerning the conditions for the use of the methods referred to in subparagraph (a);
 - c detailed rules may be adopted concerning necessary documents and procedures as well as minimum requirements for the methods referred to in subparagraph (a); and
 - d it may be decided that certain specific control methods shall not be used as a part of control programmes.
- 2 The provisions referred to in paragraph 1(a), (b) and (c) shall not apply to methods using substances or techniques covered by Community legislation on animal nutrition, food additives or veterinary medicinal products.

CHAPTER V

TRADE

Article 9

Intra-Community trade

- 1 As from the dates mentioned in Annex I, column 5, at the latest, flocks and herds of origin of the species listed in column 2 shall be tested for the zoonoses and zoonotic agents listed in column 1 prior to any dispatching of the live animals, or hatching eggs, from the food business of origin. The date and the result of testing shall be included in the relevant health certificates provided for in Community legislation.
- 2 The Member State of destination may, in accordance with the procedure referred to in Article 14(2), be authorised for a transitional period to require that the results of the tests to be referred to in the relevant health certificates for consignments of animals and hatching eggs subject to testing in the Member State of dispatch fulfil the same criteria as regards salmonella as those laid down under its approved national programme, in accordance with Article 5(5), for consignments despatched within its territory.

The authorisation may be withdrawn in accordance with the same procedure.
- 3 The special measures concerning salmonella that applied to live animals dispatched to Finland and Sweden prior to the entry into force of this Regulation shall continue to apply as if they had been authorised in accordance with paragraph 2.

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4 Without prejudice to Article 5(6), specific rules concerning the setting by Member States of the criteria referred to in Article 5(5) and in paragraph 2 above, may be laid down in accordance with the procedure referred to in Article 14(2).

Article 10

Imports from third countries

1 As from the dates mentioned in Annex I, column 5, admission to or retention on the lists of third countries provided for in Community legislation, for the relevant species or category, from which Member States are authorised to import those animals or hatching eggs covered by this Regulation shall be subject to submission to the Commission by the third country concerned of a programme equivalent to those provided for under Article 5 and its approval in accordance with this Article. The programme shall give details of the guarantees offered by that country as regards inspections and controls for zoonoses and zoonotic agents. Those guarantees must be at least equivalent to the guarantees provided for by this Regulation. The Food and Veterinary Office of the Commission shall be closely involved in monitoring to verify whether equivalent control programmes exist in third countries.

2 These programmes shall be approved in accordance with the procedure referred to in Article 14(2), provided that the equivalence of the measures described under the programme, with the relevant requirements applicable under Community rules, is objectively demonstrated. Alternative guarantees to those provided for in this Regulation may be allowed in accordance with that procedure, provided that they are not more favourable than those applicable to intra-Community trade.

3 For third countries with which a regular trade flow is established, the provisions of Article 5(7) and Article 6(1) concerning time periods for the submission and approval of programmes shall apply. For third countries establishing or resuming a trade flow, the time periods provided for in Article 6 shall apply.

4 Flocks and herds of origin of species listed in Annex I, column 2, shall be tested prior to any dispatching of the live animals or hatching eggs from the food business of origin. Flocks and herds shall be tested for the zoonoses and zoonotic agents listed in Annex I, column 1, or, if necessary to achieve the objective of equivalent guarantees laid down in paragraph 1, such zoonoses and zoonotic agents as may be specified in accordance with the procedure referred to in Article 14(2). The date and the result of testing shall be included in the relevant import certificates, for which the models laid down by Community legislation shall be amended accordingly.

5 The Member State of final destination may be authorised, in accordance with the procedure referred to in Article 14(2), to require for a transitional period that the results of the testing referred to in paragraph 4 fulfil the same criteria as those laid down under its national programme, in accordance with Article 5(5). The authorisation may be withdrawn and, without prejudice to Article 5(6), specific rules concerning such criteria may be laid down, in accordance with the procedure referred to in Article 14(2).

6 Admission to or retention on the lists of third countries provided for in Community legislation, for the relevant category of products, from which Member States are authorised to import those products covered by this Regulation shall be subject to submission to the Commission by the third country concerned of guarantees equivalent to those provided for by this Regulation.

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CHAPTER VI

LABORATORIES

Article 11

Reference laboratories

1 Community reference laboratories for the analysis and testing of zoonoses and zoonotic agents listed in Annex I, column 1, shall be designated in accordance with the procedure referred to in Article 14(2).

2 The responsibilities and tasks of the Community reference laboratories, in particular with regard to coordination of their activities and those of the national reference laboratories, shall be laid down in accordance with the procedure referred to in Article 14(2).

3 Member States shall designate national reference laboratories for the analysis and testing of zoonoses and zoonotic agents listed in Annex I, column 1. The names and addresses of laboratories shall be communicated to the Commission.

4 Certain responsibilities and tasks of the national reference laboratories, in particular with regard to coordination of their activities and those of the relevant laboratories in the Member States designated under Article 12(1)(a), may be laid down in accordance with the procedure referred to in Article 14(2).

Article 12

Approval of laboratories, quality requirements and approved testing methods

1 Laboratories participating in control programmes pursuant to Articles 5 and 7 shall, for the purposes of analysing samples to test for the presence of zoonoses and zoonotic agents referred to in Annex I, column 1:

- a be designated by the competent authority; and
- b apply quality assurance systems that conform to the requirements of the current EN/ISO standard at the latest within 24 months of entry into force of this Regulation or within 24 months of the addition of new zoonoses or zoonotic agents to Annex I, column 1.

2 Laboratories shall regularly participate in collaborative testing organised or coordinated by the national reference laboratory.

3 Testing for the presence of zoonoses and zoonotic agents referred to in Annex I, column 1, shall be carried out using the methods and protocols recommended by international standardisation bodies, as reference methods.

Alternative methods may be used if they have been validated in accordance with internationally recognised rules and offer equivalent results to those obtained by the relevant reference method.

Where necessary, other methods for testing may be approved in accordance with the procedure referred to in Article 14(2).

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Changes to legislation: There are outstanding changes not yet made to Regulation (EC) No 2160/2003 of the European Parliament and of the Council. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

CHAPTER VII

IMPLEMENTATION

Article 13

Implementing and transitional measures

Appropriate transitional or implementing measures, including the necessary amendments to the relevant health certificates, may be adopted in accordance with the procedure referred to in Article 14(2).

Article 14

Committee procedure

1 The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Regulation (EC) No 178/2002 (hereinafter referred to as ‘the Committee’).

2 Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3 The Committee shall adopt its rules of procedure.

Article 15

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on any matter within the scope of this Regulation that could have a significant impact on public health and, in particular, before proposing Community targets in accordance with Article 4 or specific control methods in accordance with Article 8.

Article 16

Report on financial arrangements

1 The Commission shall, within three years of the entry into force of this Regulation, submit a report to the European Parliament and to the Council.

2 The report shall discuss:

- a the arrangements in place, at Community and national level, to finance measures taken to control zoonoses and zoonotic agents; and
- b the effect that such arrangements have on the effectiveness of those measures.

3 The Commission shall, if appropriate, accompany its report with relevant proposals.

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4 Member States shall, on request, provide the Commission with all the assistance necessary to enable it to prepare its report.

CHAPTER VIII

GENERAL AND FINAL PROVISIONS

Article 17

Community controls

1 Experts from the Commission shall carry out on-the-spot checks, in cooperation with the competent authorities of Member States, in order to ensure that the provisions of this Regulation, rules adopted pursuant thereto and any safeguard measures are applied uniformly. A Member State on whose territory checks are made shall provide the experts with all the assistance necessary for carrying out their duties. The Commission shall inform the competent authority of the results of the checks made.

2 Rules for the implementation of this Article, in particular those governing the procedure for cooperation with national competent authorities, shall be laid down under the procedure referred to in Article 14(2).

Article 18

Entry into force

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply as from six months following its entry into force.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

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ANNEX I

SPECIFIED ZONOSSES AND ZONOTIC AGENTS FOR WHICH
COMMUNITY TARGETS FOR THE REDUCTION OF PREVALENCE
ARE TO BE ESTABLISHED PURSUANT TO ARTICLE 4

1. Zoonosis or zoonotic agent	2. Animal population	3. Stage of food chain	4. Date by which target must be established ^a	5. Date from which testing must take place
All salmonella serotypes with public health significance	Breeding flocks of <i>Gallus gallus</i>	Primary production	[^{F1} 18 months after the date of entry into force of this Regulation.]	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Laying hens	Primary production	24 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Broilers	Primary production	36 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Turkeys	Primary production	48 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Herds of slaughter pigs	Slaughter	48 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4
All salmonella serotypes with public health significance	Breeding herds of pigs	Primary production	60 months after the date of entry into force of this Regulation.	18 months after the date referred to in column 4

^a These dates are based on the assumption that comparable data on prevalence will be available at least six months before the establishment of the target. If such data were not available, the date for the establishment of the target would be postponed accordingly.

Textual Amendments

F1 Substituted by Commission Regulation (EC) No 1003/2005 of 30 June 2005 implementing Regulation (EC) No 2160/2003 as regards a Community target for the reduction of the prevalence of certain salmonella serotypes in breeding flocks of *Gallus gallus* and amending Regulation (EC) No 2160/2003 (Text with EEA relevance).

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ANNEX II

CONTROL OF ZOOSES AND ZOO NOTIC AGENTS LISTED IN ANNEX I

A. General requirements for national control programmes

The programme must take into account the nature of the zoonosis and/or zoonotic agent concerned and the specific situation in the Member State. It must:

- (a) state the aim of the programme taking into consideration the importance of the zoonosis or zoonotic agent concerned;
- (b) comply with the minimum sampling requirements laid down in part B;
- (c) where relevant, comply with the specific requirements laid down in parts C to E; and
- (d) specify the following points:
 1. General
 - 1.1. The occurrence of the zoonosis or zoonotic agent concerned in the Member State with specific reference to the results obtained in the framework of monitoring in accordance with Article 4 of Directive 2003/99/EC.
 - 1.2. The geographical area or, where appropriate, the epidemiological units, in which the programme will be implemented.
 - 1.3. The structure and organisation of the relevant competent authorities.
 - 1.4. Approved laboratories where samples collected within the programme are analysed.
 - 1.5. Methods used in the examination of the zoonosis or zoonotic agent.
 - 1.6. Official controls (including sampling schemes) at feed, flock and/or herd level.
 - 1.7. Official controls (including sampling schemes) at other stages of the food chain.
 - 1.8. Measures taken by the competent authorities with regard to animals or products in which zoonoses or zoonotic agents have been detected, in particular to protect public health; and any preventive measures taken, such as vaccination.
 - 1.9. Relevant national legislation, including any national provisions concerning the activities referred to in Article 1(3)(b).
 - 1.10. Any financial assistance provided to food and feed businesses in the context of the national control programme;
 2. Concerning food and feed businesses covered by the programme
 - 2.1. The structure of the production of the given species and products thereof.
 - 2.2. The structure of the production of feed.
 - 2.3. Relevant guides for good animal husbandry practices or other guidelines (mandatory or voluntary) defining at least:
 - hygiene management at farms,

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- measures to prevent incoming infections carried by animals, feed, drinking water, people working at farms, and
 - hygiene in transporting animals to and from farms.
- 2.4. Routine veterinary supervision of farms.
 - 2.5. Registration of farms.
 - 2.6. Record-keeping at farms.
 - 2.7. Documents to accompany animals when dispatched.
 - 2.8. Other relevant measures to ensure the traceability of animals.

B. Minimum sampling requirements

1. After the relevant control programme referred to in Article 5 has been approved, food business operators must have samples taken and analysed to test for the zoonoses and zoonotic agents listed in Annex I, column 1, respecting the minimum sampling requirements set out in the following table.

1. Zoonosis or zoonotic agent	2. Animal population	3. Phases of production which sampling must cover
All salmonella serotypes with public health significance	Breeding flocks of <i>Gallus gallus</i> :	
	— rearing flocks	— day-old chicks
		— four-week-old birds
		— two weeks before moving to laying phase or laying unit
	— adult breeding flocks	— every second week during the laying period
All salmonella serotypes with public health significance	Laying hens:	
	— rearing flocks	— day-old chicks
		— pullets two weeks before moving to laying phase or laying unit
	— laying flocks	— every 15 weeks during the laying phase

a The results of the analysis on the samples must be known before the animals leave for the slaughterhouse.

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All salmonella serotypes with public health significance	Broilers	—	birds leaving for slaughter ^a
All salmonella serotypes with public health significance	Turkeys	—	birds leaving for slaughter ^a
All salmonella serotypes with public health significance	Herds of pigs:		
	— breeding pigs	—	animals leaving for slaughter or carcasses at the slaughterhouse
	— slaughter pigs	—	animals leaving for slaughter or carcasses at the slaughterhouse

a The results of the analysis on the samples must be known before the animals leave for the slaughterhouse.

2. The requirements laid down in point 1 are without prejudice to the requirements of Community legislation concerning *ante mortem* inspection.
 3. The results of the analysis must be recorded, together with the following information:
 - (a) date and place of sampling; and
 - (b) identification of the flock/herd.
 4. Immunological testing may not be used if the animals have been vaccinated, unless it has been proven that the vaccine used does not interfere with the testing method applied.
- C. Specific requirements concerning breeding flocks of *Gallus gallus*
1. The measures laid down in points 3 to 5 must be taken whenever the analysis of samples carried out in accordance with part B indicates the presence of *Salmonella enteritidis* or *Salmonella typhimurium* in a breeding flock of *Gallus gallus* in the circumstances set out in point 2.
 2.
 - (a) If the competent authority has approved the method of analysis used for samples taken in accordance with part B, it may require that the measures laid down in points 3 to 5 be taken when such analysis detects the presence of *Salmonella enteritidis* or *Salmonella typhimurium*.
 - (b) Otherwise, the measures laid down in points 3 to 5 must be taken whenever the competent authority confirms a suspicion of the presence of *Salmonella enteritidis* or *Salmonella typhimurium* arising from the analysis of samples carried out in accordance with part B.
 3. Non-incubated eggs from the flock must be destroyed.

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However, such eggs may be used for human consumption if they are treated in a manner that guarantees the elimination of *Salmonella enteritidis* and *Salmonella typhimurium* in accordance with Community legislation on food hygiene.

4. All birds, including day-old chicks, in the flock must be slaughtered or destroyed so as to reduce as much as possible the risk of spreading salmonella. Slaughtering must be carried out in accordance with Community legislation on food hygiene. Products derived from such birds may be placed on the market for human consumption in accordance with Community legislation on food hygiene and, once applicable, part E. If not destined for human consumption, such products must be used or disposed of in accordance with Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption⁽²¹⁾.
 5. Where eggs for hatching from flocks in which *Salmonella enteritidis* or *Salmonella typhimurium* is present are still present in a hatchery, they must be destroyed or treated in accordance with Regulation (EC) No 1774/2002.
- D. Specific requirements concerning flocks of laying hens
1. With effect from 72 months after entry into force of this Regulation, eggs must not be used for direct human consumption (as table eggs) unless they originate from a commercial flock of laying hens subject to a national programme established under Article 5 and not under official restriction.
 2. Eggs originating from flocks with unknown health status, that are suspected of being infected or from infected flocks may be used for human consumption only if treated in a manner that guarantees the elimination of all salmonella serotypes with public health significance in accordance with Community legislation on food hygiene.
 3. When birds from infected flocks are slaughtered or destroyed, steps must be taken to reduce the risk of spreading zoonoses as far as possible. Slaughtering must be carried out in accordance with Community legislation on food hygiene. Products derived from such birds may be placed on the market for human consumption in accordance with Community legislation on food hygiene and, once applicable, part E. If not destined for human consumption, such products must be used or disposed of in accordance with Regulation (EC) No 1774/2002.
- E. Specific requirement concerning fresh meat
1. With effect from 84 months after entry into force of this Regulation, fresh poultry meat from animals listed in Annex I may not be placed on the market for human consumption unless it meets the following criterion:

Salmonella: absence in 25 grams
 2. Within 72 months of entry into force of this Regulation, detailed rules for this criterion will be laid down in accordance with the procedure referred to in Article 14(2). These will specify, in particular, sampling schemes and analytical methods.
 3. The criterion laid down in paragraph 1 does not apply to fresh poultry meat destined for industrial heat treatment or another treatment to eliminate salmonella in accordance with Community legislation on food hygiene.

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ANNEX III

Specific criteria to determine salmonella serotypes with public health significance

When determining which are the salmonella serotypes with public health significance to which Community targets will apply, account must be taken of the following criteria:

1. the most frequent salmonella serotypes in human salmonellosis on the basis of data collected through EC monitoring systems;
2. the route of infection (that is, the presence of the serotype in relevant animal populations and feed);
3. whether any serotype shows a rapid and recent ability to spread and to cause disease in humans and animals;
4. whether any serotypes show increased virulence, for instance as regards invasiveness, or resistance to relevant therapies for human infections.

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- (1) OJ C 304 E, 30.10.2001, p. 260.
- (2) OJ C 94, 18.4.2002, p. 18.
- (3) Opinion of the European Parliament of 15 May 2002 (OJ C 180 E, 31.7.2003, p. 160), Council Common Position of 20 February 2003 (OJ C 90 E, 15.4.2003, p. 25) and Position of the European Parliament of 19 June 2003 (not yet published in the Official Journal). Council Decision of 29 September 2003.
- (4) OJ L 62, 15.3.1993, p. 38. Directive as last amended by Council Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).
- (5) OJ L 113, 30.4.1997, p. 9.
- (6) OJ 121, 29.7.1964, p. 1977/64. Directive as last amended by Commission Regulation (EC) No 1226/2002 (OJ L 179, 9.7.2002, p. 13).
- (7) OJ L 46, 19.2.1991, p. 19. Directive as last amended by Regulation (EC) No 806/2003.
- (8) See page 31 of this Official Journal.
- (9) OJ L 302, 31.12.1972, p. 28. Directive as last amended by Commission Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).
- (10) OJ L 303, 31.10.1990, p. 6. Directive as last amended by Regulation (EC) No 806/2003.
- (11) OJ L 371, 31.12.1994, p. 36.
- (12) OJ L 53, 9.3.1995, p. 31.
- (13) OJ L 105 9.5.1995, p. 40. Decision as last amended by Decision 97/278/EC (OJ L 110, 26.4.1997, p. 77).
- (14) OJ L 105, 9.5.1995, p. 44. Decision as last amended by Decision 97/278/EC.
- (15) OJ L 109, 16.5.1995, p. 44. Decision as last amended by Decision 97/278/EC.
- (16) OJ L 243, 11.10.1995, p. 21. Decision as last amended by Decision 98/227/EC (OJ L 87, 21.3.1998, p. 14).
- (17) OJ L 243, 11.10.1995, p. 25. Decision as last amended by Decision 98/227/EC.
- (18) OJ L 243, 11.10.1995, p. 29. Decision as last amended by Decision 98/227/EC.
- (19) OJ L 31, 1.2.2002, p. 1.
- (20) OJ L 184, 17.7.1999, p. 23.
- (21) OJ L 273, 10.10.2002, p. 1. Regulation as last amended by Commission Regulation (EC) No 808/2003 (OJ L 117, 13.5.2003, p. 1).

Status:

Point in time view as at 01/07/2005.

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